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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/432,881	11/02/1999	MICHELINE MARKEY	15662-000900	1727

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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/432,881

Applicant(s)

MARKEY ET AL.

Examiner

Shirley V. Gembah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-26, 32-34, 47-55 and 97-151 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 32-34, 47-55, 97, 98, 105-110, 112, 130 and 143-151 is/are rejected.
- 7) ☒ Claim(s) 99 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The response filed **1/29/07** presents remarks and arguments to the office action mailed **8/03/06**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 99 is objected to because of the following informalities: There should be a space between 98 and in. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 99 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites (see 2 last lines of instant claim 99) wherein the fed mode inducing agent is sufficiently potent that onset of said fed mode results from release of

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an amount of said fed mode inducing agent that is less than 500. The claim fails to show steps that resulted in this calculation of release drug of the fed mode inducing agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 32-34, 47-55, 97-98, 105-110, 112, 130 and 143-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al US 6,120,803.

Wong et al teach an active dosage form retained in the stomach for prolong delivery, wherein the polymer matrix swells in the stomach (see abstract) wherein the compound is arginine (see col. 6, line 17) as in claims 1, 3, 32 105 and 130 item e, a n alkaline such as sodium satls (see col. 6, lines 22-26) as in the instant claims 1 and 105 item b, wherein the composition is retained in the a solid matrix with said drug in a sustained manner (see col. 5, lines 28-42 and col. 6, lines 32-41) as in claims 2 and 106 wherein the said mode inducing agent is separate from the solid matrix is taught because the fed mode agent is arginine (see col. 6, line 17) is different from the solid matrix-a polymer matrix (see col. 5, line 28-31) as in claim 4 and 108, and the size of the solid matrix is sufficiently large to promote retention is taught (see col. 5, lines 55-67) in the reference as soluble polymers (soluble polymers reacts with liquid and swell to more than twice its size) known to one of ordinary skill in the art a common

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characteristics of water-soluble polymers) as taught in claims 5-6 and 109-110 (see also col. 9 lines 44-45) for support of the above statement. As to claim 97 and 143 (see abstract) wherein the first solid matrix (see col. 2, lines 58-67 and col. 7, lines 17-25) wherein the composition comprises a common single matrix is taught (see col. 7, lines 17-19) as in claim 98. As to the dosage of arginine in claims 32-34, Wong teaches (see col. 21, lines 34-47) the active agent is in a dosage form of 200 mg. Arginine is the active form thus the dosage is within the claim limitations of 32-33. With regards to claim 34, the dosage amount is within the purview of the skilled artisan to optimize and as taught by Wong et al. using the term "if" suggest that these dosage forms varies depending on how many times per day administered (see col. 21, lines 34-47).

The reference further teaches with regards to claim 47-48, 52, and 143-144 as discussed and in reference to the osmotic pressure the reference teaches (see col. 6, lines 59-67) and the teachings above is applied here, wherein the matrix is of cellulose polymer, hydroxymethylcellulose, the matrix is a water soluble, and the water soluble matrix is cellulosic, sodium carboxymethylcellulose (see col. 5, lines 55-67) as in claims 49-55, 145-147, 149-151. The reference also teaches the fed mode agent is a sugar alcohol-mannitol is a sugar alcohol (see col. 6, line 14) as in claim 112.

The instant claims differ in such that it did not exactly as recited in the instant claims 3 and 107 wherein the fed inducing agent resides in a surface coating or layer on the said solid matrix permitting substantially immediate release. Although, the reference did not teach exactly as claimed, it however, teaches that these agents are in a solid matrix (see col. 7, lines 17-33) wherein the fed mode inducing agent is a unitary

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compressed dispersion of a solid active agent in a gel forming erodible polymer and may contain a gastric emptying delaying agent that increases the retention time of the dosage form in the stomach. As explained above the active agent arginine meets the limitation of fed mode reducing agent of claim 1. Since as taught the gastric emptying delaying agent may be combined with the composition with the active agent for local delivery to the environment of use it may be coated on the dosage form to provide the desired physiological response (see col. 7, lines 28-32) therefore reside in a surface coating and when in the stomach the gastric fluid will cause the polymer to break by breaking the bonds as swelling could lead to the formation of a very loose particles and prolong retention of the solid matrix with a substantial release. Note that substantially has been determined to be any amount.

Thus, at the time of filing this application, one of ordinary skill in the art would have found the instant pharmaceutical composition obvious over the reference since the reference teaches a fed mode inducing agent(s) for the claimed invention. The reference is relied upon here because it has conveyed all the necessary teachings for one of ordinary skill in the art. Accordingly, one of ordinary skill in the art would thus have been motivated to prepare a pharmaceutical composition embraced by the guidance and expect a reasonable success in doing so because the teachings are to a pharmaceutical agent with a prolong release agent for gastric retention with a swellable dosage matrix. The poly soluble polymers are the same as that of the claimed invention. Thus, the skilled artisan would expect the close structural similarities of the compounds to possess similar properties.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembah whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
4/11/07


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER